

Attorney Docket No.: 6200.200-US  
Application No.: 09/921,429  
Filed: August 2, 2001  
Applicant: Lars Morch Groth  
Express Mail Label No.: EV 450789026 US



Attorney Docket No.: 6200.200-US

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARDS OF PATENT APPEALS AND INTERFERENCES**

In re Application of: Lars Morch Groth

Confirmation No.: 3993

Serial No.: 09/921,429

Group Art Unit: 3728

Filed: August 2, 2001

Examiner: Pickett, John G.

For: A needle magazine

Appeal No.:

**APPELLANTS REPLY TO EXAMINER'S ANSWER**

This reply is in response to Examiners Answer dated February 24, 2005

## **APPELLANTS REPLY TO EXAMINER'S ANSWER**

### **A. Applicants invention**

In accordance with the present invention, applicant has found that a re-arrangement in which the cavities of a needle magazine are arranged radially provides a needle magazine with unexpected advantages by allowing the needle magazine to be used as a tool for securing needle assemblies to injection devices, and not merely as a magazine for storing needle assemblies, such as the one suggested by NGUYEN which contains non-radial cavities. Applicants' have also invented a method of using their magazine to aid those who lack physical strength to fasten needles to injection pens. In particular, the method that applicants are claiming requires rotating both the magazine and the pen.

While the Examiner may be correct that that the NGUYEN et al magazine theoretically can be rotated relative to a pen, there is absolutely no indication in NGUYEN et al that such a property would be desirable when attaching or detaching a pen from a needle. Moreover, there is no motivation in the prior art to modify a pen needle magazine so that it has radial cavities, like a sewing needle magazine of Current. The Examiner is at best speculating that based on a desire to change the magazine's height, one would be motivated to rearrange the cavities of NGUYEN so that they matched the orientation of Current. But there is nothing in the record to suggest that making the NGUYEN magazine with a reduced height (and consequently larger radius) would be desirable. Thus, Appellant's invention does not provide "more of the same" as alleged by the Examiner, but an entirely new approach of using a needle magazine as a rotatable tool, this representing an unexpected and patentable advantage.

That applicants' invention relies upon basic principles of physics, such as a torque couple, or that applicants' invention is not overly complex, does not negate patentability. Applicants' have created a tool that provides real and tangible benefits to those who lack physical strength. And it is that desire to create such a tool that has lead applicants to their arrangement of cavities within a needle magazine. Moreover, it is only

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with the aid of applicants' disclosure would anyone modify the configuration of NGUYEN by combining it with Current..

**B. The Examiner fails to establish a *prima facie* case of obviousness**

The Examiner admits that no teaching, suggestion, or motivation to combine the references relied upon can be found in the references themselves, but alleges, without any factual support in the record that it was a well established principal of design to limit overall size for a portable device and that this principle applies to pen needle magazines.

Although it may be desirable for certain types of devices to reduce overall size, this is not necessarily the case for a medical device intended to be handled by typically elderly people or the infirm, who may lack dexterity or strength. Nothing in the record establishes that for a pen needle magazine smaller is better. Indeed, common sense dictates that for people who, because of age or illness, lack physical dexterity, smaller may not be desirable. Correspondingly, it was not a main object of the present invention to reduce size but to provide a needle magazine with properties allowing it to be used as a mounting tool.

Furthermore, even if one were to assume that reduction in size is desirable, the Examiner has provided no proof that a redesign of the NGUYEN et al magazine so that it would have the cavities of a sewing needle magazine would actually provide a more compact device. The Examiner simply argues that it would have a reduced height. Of course, this would likely result in a magazine with a larger radius, especially given that pen needles include hubs that have a significantly larger diameter than sewing needles. The Examiner fails to explain why having a reduced height and consequently a larger radius is so much better than having a large height and smaller radius that one of ordinary skill would be motivated to modify NGUYEN and with the cavity configuration of CURRENT.

Thus, Appellant submits that it is neither a well established principle that medical devices manipulated by hand should be as small as possible (or more accurately, as low

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or short as possible), nor that the modification corresponding to the present invention actually provides a needle magazine with overall reduced size.

Addressing In re Japikse the Examiner argues that a number of properties for the NGUYEN et al magazine perform the same function irrespective of whether pen insertion is radial or perpendicular, however, the Examiner fails to acknowledge that in respect of the needle magazine being used as a tool, there is a fundamental functional difference between a needle magazine having the needle cavities arranged radially respectively perpendicularly. Exactly this functional difference represents the present invention and is the only cognizable motivation to make such a magazine for injection pen needles.

### **C. The teachings of the cited prior art**

The NGUYEN reference actually teaches away from the present invention. The Examiner incorrectly argues that except for the figures NGUYEN et al is silent as to the orientation of the needle cavities for which reason a skilled person would also consider a different orientation thereof. Appellant submits this is not the case. In contrast, claim 1 defines an apparatus for storing a plurality of needle assemblies, comprising “a container having an upper surface including a plurality of cavities (emphasis added) for receiving each of said plurality of needle assemblies therein”. What is thus defined in the claims of NGUYEN et al must represent the strongest possible way of setting out what NGUYEN et al considered as their invention. The Examiner fails to address this clear indication.

In other words, the arrangement of the needle cavities in the upper surface as depicted in fig. 2 cannot be considered merely an embodiment of the invention but must be regarded as representing the invention *per se* and any suggestion to modify this feature must be considered against the clear teaching of NGUYEN et al.

In respect of CURRENT the Examiner argues that this reference should be evaluated not for what it teaches but for what the drawings disclose or suggest to the skilled person. Consequently the Examiner argues that CURRENT suggests a needle magazine with reduced high.

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The Applicant respectfully disagrees. CURRENT does not objectively show a needle magazine with reduced height but merely a needle magazine having certain proportions. It is only with impermissible hindsight and knowledge of the present invention that the CURRENT device represents a needle magazine with reduced height, i.e. relative to NGUYEN et al. The link between NGUYEN et al and CURRENT is only established by virtue of the present invention, and not by any well established principal of design or any teaching in NGUYEN et al or CURRENT, neither explicitly nor implicitly.

Moreover and as is stated above, even if one of ordinary skill would recognize that a height reduction would occur, there is nothing to suggest that this would motivate one of ordinary skill to make a lower and wider cylindrical magazine. Indeed, the Examiner has failed to explain why one who needs a needle magazine would prefer a reduced height (i.e. shorter) and larger radius (i.e. fatter) one and not one with a larger height and small radius. Put simply, why is short and fat better than tall and skinny other than because the Examiner says so?

#### **D. The method of the present invention**

The Examiner asserts that the degree of rotation between an injection device and a needle magazine is dependent upon the depths of the threads used for connection of a needle with an injection device, “with the specific degree of rotation being an obvious matter”. It is not entirely clear to the Appellant what the Examiner means by “specific degree,” however, in respect of claim 22 it appears that the 360 degrees rotation of the tool (i.e. needle magazine) respectively the 360 degrees rotation of the injection device is addressed.

As NGUYEN does not disclose a needle magazine that is suitable for being rotated by the user, and consequently is totally silent as to any rotation thereof, it is difficult to see how the specified rotations of both the needle magazine and the injection device in claim 22 should be an obvious design choice.

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For the reasons set out above as well as in Appellant's Brief, it is respectfully requested that the rejection of claims 19-22 be set aside.

Respectfully submitted,

Date: April 13, 2005



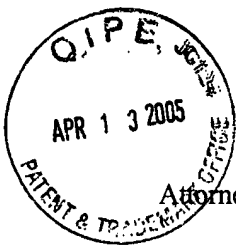
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Marc A. Began, Reg. No. 48,829  
Novo Nordisk Inc.  
100 College Road West  
Princeton, NJ 08540  
(609) 987-5800

**CUSTOMER NUMBER**

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1. Appellants Reply to Examiner's Answer (6 pages) (in triplicate)

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